

Preventative Osteopathic Manipulative Treatment and the Elderly Nursing Home Resident: A Pilot Study

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Context: Elderly nursing home residents are generally in poor health. Many residents report pain on a daily basis, few are independent in their activities of daily living, and most take a large number of medications.

Objective: To investigate the benefits elderly nursing home residents may receive from preventative osteopathic manipulative treatment (OMT) designed to optimize structure and function and enhance their bodies' homeostatic mechanisms.

Methods: Volunteer nursing home residents were randomly assigned to 1 of 3 groups: (1) OMT, (2) light touch (LT), or (3) treatment as usual (TAU). The OMT group received an OMT protocol twice per month for 5 months, for a total of 10 visits. The LT group received a light-touch protocol meant to simulate OMT at the same frequency as the OMT group. The TAU group received no intervention. Participant health information from Minimum Data Set assessments was monitored during the study, along with hospitalizations, emergency room visits, and outpatient procedures. The nursing home personnel and the participants' attending physicians were blinded to treatment group assignment.

Results: Twenty-one participants completed the study: 8 in the OMT group, 6 in the LT group, and 7 in the TAU group. The OMT and LT groups had fewer hospitalizations ($P=.04$) and decreased medication usage ($P=.001$) compared with the TAU group.

Conclusion: Twice monthly OMT and LT protocols reduced the number of hospitalizations and decreased medication usage in elderly nursing home residents. (ClinicalTrials.gov number NCT01000142)

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Osteopathic medicine began as an alternative approach to patient care that focused special attention on the musculoskeletal system in the management of disease. Historically, osteopathic physicians included osteopathic manipulative treatment (OMT) as part of their regular plan of care for almost all medical conditions.¹⁻³ This practice was based on a philosophy that the patient's body possesses self-healing and self-regulating mechanisms and that structure and function are interrelated.⁴ Currently, many osteopathic physicians no longer include OMT as part of their regular plan of care, even though the profession still professes a holistic philosophy.⁵⁻⁷ Many physicians cite insufficient time,^{8,9} evidence,^{8,9} and clinical training,⁸⁻¹⁰ as well as difficulties associated with reimbursement,^{9,11,12} as reasons to no longer provide this service.

For elderly nursing home residents, the ability to take care of oneself is diminished by underlying diseases. According to osteopathic philosophy, optimizing the nursing home resident's physical structure through OMT should enhance his or her body's homeostatic mechanisms. The purpose of the current pilot study was to investigate the effects of preventative OMT on the health of elderly nursing home residents. We also sought to establish protocols for use in a larger study on the effect of OMT on the morbidity and mortality of elderly nursing home residents. We hypothesized that a short, 15-minute OMT protocol administered bimonthly would have a positive impact on the health of elderly nursing home residents. We also expected that a light touch (LT) protocol would have a positive impact on the residents' health because of social interaction and physical contact, but that the impact would

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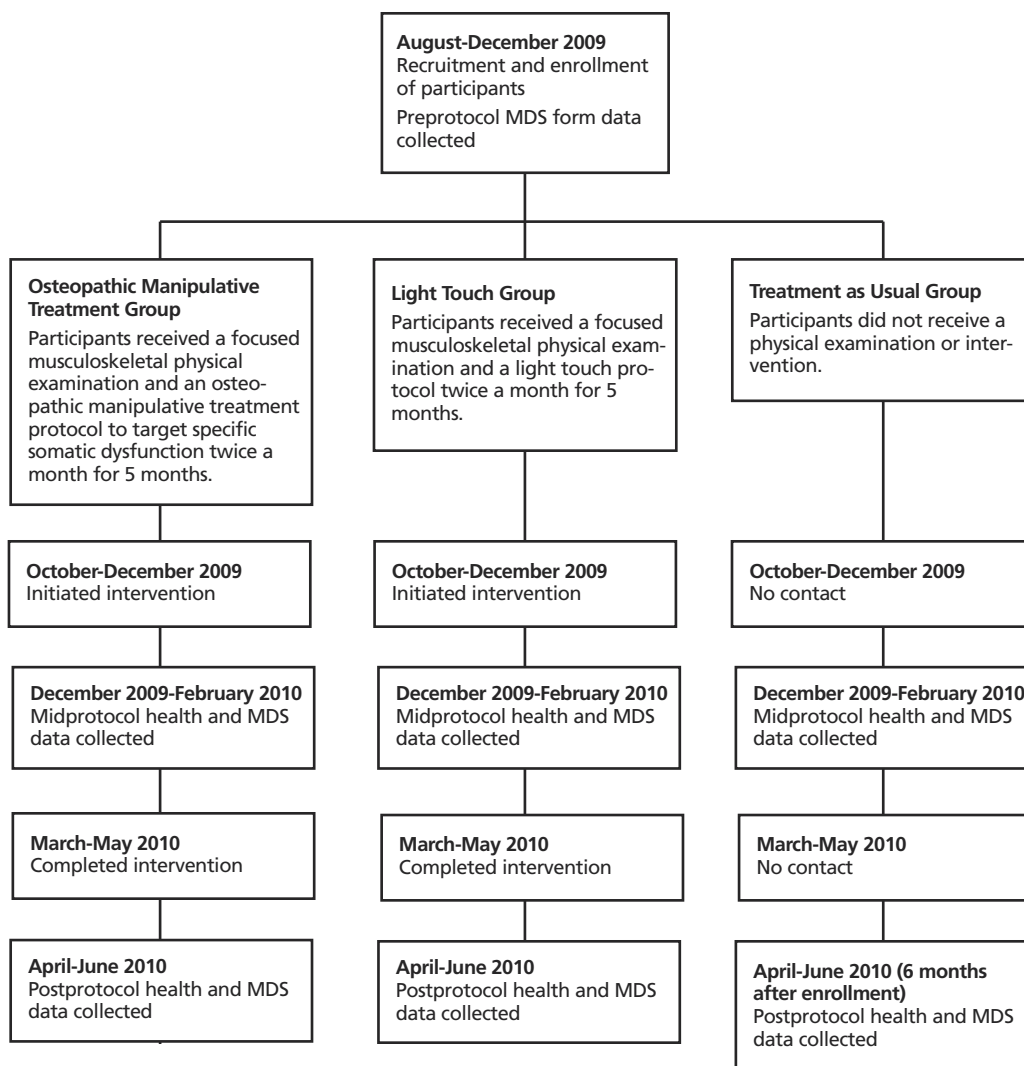


Figure 1. Experimental design for a pilot study on preventative osteopathic manipulative treatment in elderly nursing home residents. **Abbreviation:** MDS, Minimum Data Set.

be less than that of the OMT protocol when compared with a treatment as usual (TAU) group.

Methods

The current pilot study took place from August 2009 to May 2010. The study was approved by the A.T. Still University-Kirksville College of Osteopathic Medicine Institutional Review Board #1 and was registered with ClinicalTrials.gov (study #NCT01000142).

Participants and Setting

Men and women aged 65 to 100 years who were residents of 1 of 2 area nursing homes in Kirksville, Missouri, were eligible for the current study. Exclusion criteria were life

expectancy of less than 6 months, terminal cancer, active tuberculosis, inability to cooperate with the treating physicians, inability to tolerate OMT, and known metabolic bone disease that would put the resident at risk for a pathological fracture, such as Paget disease or hypoparathyroidism.

After approval was received from the directors of both nursing homes, nursing home resident medical records were reviewed to screen for eligibility. The primary care physician of each potential participant was contacted to determine eligibility and to obtain permission to approach the resident or the resident’s guardian to offer study enrollment. Once physician approval was received and eligibility was verified by a study investigator (C.H. or C.S.), the res-

ident and, when applicable, the resident's guardian or the person with power of attorney was approached to obtain informed consent for resident participation.

Study recruitment and enrollment began in August 2009 and continued through mid-December 2009; treatment protocols were administered beginning in mid-October 2009 (Figure 1). Treatment protocols were conducted during the winter months, when deaths in the elderly due to ischemic heart disease, cerebrovascular disease, and acute respiratory diseases peak in temperate regions around the world¹³⁻²⁸; thus, the winter season provides the greatest opportunity for disease prevention.

Participants were randomly assigned to 1 of the 3 following groups: (1) OMT, (2) LT, or (3) TAU. Stratified, blocked randomization was performed, stratifying on nursing home, sex, and age (65-80 years and older than 80 years) with block sizes of 3. Group allocation was concealed using opaque envelopes. The personnel who completed the Minimum Data Set (MDS) assessments and all health care personnel who made health care decisions for the participants were blinded to participant treatment group assignment. Participants in the OMT and LT groups were also blinded to their treatment group assignment.

Treatment Protocols

Participants in the OMT and LT groups received a focused musculoskeletal physical examination twice a month for 5 months (10 visits). This physical examination included evaluation of the cervical, thoracic, and lumbar spine; sacrum; pelvis; and ribs.

The OMT group received an OMT protocol at each visit that addressed optimization of homeostatic mechanisms and targeted somatic dysfunction found during that visit's physical examination (Figure 2). The treating physicians (K.T.S., E.J.S., C.S., and 5 other physicians), performed OMT on the basis of a standardized protocol meant to optimize autonomic nervous system functioning and lymphatic drainage (Figure 2). Within the confines of the OMT protocol, the treating physicians could perform direct, indirect, or combined techniques to the thoracic inlet and abdominal diaphragm regions. Physicians were also expected to treat all clinically significant somatic dysfunctions found during that visit's physical examination. Any OMT provided outside the standardized protocol was applied on the basis of the physical examination findings, and techniques were at the discretion of the treating physician. The following OMT techniques could be used: articular/springing; balanced ligamentous tension; cranial; facilitated positional release; high-velocity, low-amplitude; muscle energy; myofascial release; soft tissue; Still; strain-counterstrain; and visceral manipulation. Because most of the nursing home residents were sedentary and likely to have osteoporosis, the treating physicians adjusted the OMT to stay within the tolerance of the participants. Par-

1. Focused osteopathic musculoskeletal examination
2. Paraspinal muscle inhibition and/or soft tissue kneading or stretching (1-2 minutes)
3. Rib raising and/or rib mobilization (45-60 seconds)
4. Abdominal diaphragm release technique (20-60 seconds)
5. Abdominal mesenteric/colon release technique (20-60 seconds)
6. Thoracic inlet release technique (20-60 seconds)
7. Hip flexion/extension passive range of motion technique (20-60 seconds)
8. Shoulder range of motion with pectoral traction (20-60 seconds)
9. Cervical paraspinal muscle inhibition and/or soft tissue kneading or stretching (30-60 seconds)
10. Suboccipital release technique (15-30 seconds)
11. Variable techniques to treat clinically significant somatic dysfunction of each participant

Figure 2. Osteopathic manipulative treatment protocol administered to nursing home residents. The protocol lasted 10 to 15 minutes, and participants could be seated, lateral recumbent, or supine. All techniques were performed within the patient's tolerance.

ticipants were informed that some soreness could be expected because tight muscles would be stretched and joints would be mobilized as part of improving musculoskeletal function.

The LT group received a protocol meant to simulate OMT but with substantially diminished forces (Figure 3). The LT protocol was not expected to make musculoskeletal changes.

The total visit time for each person in the OMT group was 10 to 15 minutes and the total visit time for each person in the LT group was 5 to 10 minutes. The TAU group received no intervention.

The protocol period ended for all participants by May 2010. To guarantee an absolute minimal possibility of injury or other adverse reaction, all osteopathic examinations, assessments, and treatments were performed by trained and licensed osteopathic physicians who either specialized in osteopathic manipulative medicine or were in residency training in osteopathic manipulative medicine.

Measurements

On receipt of informed consent from the nursing home resident and guardian, if applicable, the resident's most recent MDS version 2.0 assessment was obtained. The MDS forms, which are used to record patient health data

ORIGINAL CONTRIBUTION

from admission, quarterly, and annual assessments, are part of comprehensive clinical assessment tools required by the Centers for Medicare & Medicaid Services for nursing homes. The MDS data are used to determine payment.²⁹ The data recorded on the forms, which included residents' medical problems, medication usage, and level of activities of daily living (ADLs), provided a comprehensive assessment of the health status of the nursing home residents before the study.

The 2.0 version of the MDS forms were used nationally at nursing homes from 1995 to September 2010 (ie, during the study period). The MDS data have demonstrated reasonable validity for research purposes.^{30,31} Various MDS assessments are performed at admission, quarterly, annually, and when there is a substantial change in the patient health status. Therefore, all participants in the current study had at least 1 MDS assessment completed within the 90-day window prior to enrollment in the study and within the 90-day window after the protocol period.

The MDS assessments and forms were completed by trained personnel at each nursing home. The personnel who completed the MDS assessments and all health care personnel who made health care decisions for the participants were blinded to study group assignment. Throughout the protocol period and for 3 months after the protocol period, retrospective medical record reviews were conducted for all participants. The medical record reviews included midprotocol and postprotocol MDS data, history of hospitalizations, emergency room visits, outpatient procedures, and mortality.

The MDS data used in the study were selected from the assessments already being completed by the nursing home personnel, and no attempt was made to conduct additional MDS assessments for the study. The preprotocol MDS data were from the assessment completed closest to

and within the 90-day window prior to enrollment. The postprotocol MDS data were from the assessment completed within the 90-day window after the protocol period, starting 6 months after enrollment for participants in the TAU group and 30 days after the final treatment for participants in the OMT and LT groups.

Data extracted from the MDS assessments for use in the current study (*Appendix*) included information on physical functioning (ADLs, passive range of motion, voluntary movement, and falls), cognition and affect (memory, decision making, delirium, depression and anxiety, and time involved in activities), and health care utilization (infections, pain, stability of conditions, change in care needs, and number of medications). Data extracted for the current study were available from all versions of the MDS forms (ie, admission, quarterly, annual, and change in status). Memory (short- and long-term; item B2), Cognitive Skills for Daily Decision Making (item B4), Infections (item I2), Accidents (ie, number of falls; item J4), Stability of Conditions (item J5), Overall Change in Care Needs (item Q2), and Number of Medications (item O1) were extracted as recorded on the MDS forms for use as outcome measures. Other outcome measures, including ADL dependence, delirium, mood, passive range of motion, voluntary movement, pain symptoms, and time involved in activities were calculated from the MDS data as described in the following paragraphs.

ADL dependence—The ADL dependence measure was calculated from the 11 self-performance and support assessment scores from items G1 (ADL Self-Performance) and G2 (Bathing) on the MDS form using the following point system adapted from the RUG-III version 5.12 Calculation Worksheet³²: The participant received 1 point for each ADL item recorded on the MDS form as independent or requiring supervision; 3 points for activities requiring limited assistance; 4 points for activities requiring extensive assistance or when performance was totally dependent on assistance from 1 person; and 5 points for activities requiring extensive assistance, when performance was totally dependent on assistance from 2 or more persons, or when the activity occurred 2 or fewer times during the 7-day observation period. Therefore, the ADL dependence measure could range from 11 (total independence) to 55 (total dependence).

Delirium—The delirium measure was calculated as the sum of the scores recorded for item B5 (Indicators of Delirium) on the MDS form. Six separate behaviors were assessed on the basis of the presence or absence of the behavior and time of onset of each behavior observed within the past 7 days. The total delirium measure could range from 0 (no behaviors present) to 12 (new onset of all behaviors assessed).

1. Focused osteopathic musculoskeletal examination
2. Contact ribs so as to simulate rib raising and paraspinal muscle inhibition (45-60 seconds)
3. Contact lower rib margin so as to simulate abdominal diaphragm release technique (15-30 seconds)
4. Palpate the 4 quadrants of the abdomen so as to simulate the abdominal mesenteric/colon release (15-30 seconds)
5. Contact shoulders so as to simulate thoracic inlet release technique (15-30 seconds)
6. Contact suboccipital region so as to simulate suboccipital release technique (15-30 seconds)

Figure 3. Light touch protocol administered to elderly nursing home residents. The protocol lasted 5 to 10 minutes, and participants could be seated, lateral recumbent, or supine.

Mood—The mood measure was calculated as the number of indicators scored as exhibited from item E1 (Indicators of Depression, Anxiety, Sad Mood) on the MDS form. Sixteen behaviors were assessed on the basis of the presence or absence of each behavior observed within the past 30 days. The participant received 1 point for each behavior recorded on the MDS form as being exhibited at least once in the past 30 days. The total mood measure could range from 0 (no behaviors exhibited) to 16 (all behaviors exhibited at least once in the past 30 days).

Passive range of motion and voluntary movement—The passive range of motion measure and voluntary movement measure were calculated as the sum of the scores recorded for items G4 (Functional Limitation in Range of Motion) sections A (Range of Motion) and B (Voluntary Movement) on the MDS form, respectively. Six regions of the body (neck, arms, hands, legs, feet, and other) were assessed for severity of limitations of range of motion and loss of voluntary movement that interfered with daily functions or put the resident at risk for injury within the past 7 days. The total passive range of motion measure and the voluntary motion measure could range from 0 (no limitation/loss) to 12 (full limitation/loss).

Pain symptoms—The pain symptoms measure was calculated as the product of the scores recorded for item J2 (Pain Symptoms) on the MDS form. Pain frequency and intensity were determined on the basis of resident complaints or behaviors observed in the past 7 days. The total pain symptom measure could range from 0 (no pain) to 6 (daily horrible or excruciating pain).

Time involved in activities—The time involved in activities measure was calculated using the scores recorded for item N2 (Average Time Involved in Activities) on the MDS form. The participant was given 3 points if they were involved in activities more than two-thirds of the time, 2 points if they were involved from one-third to two-thirds of the time, 1 point if they were involved less than one-third of the time, and 0 points if they were not involved in activities. The time involved in activities measure could range from 0 (not involved) to 3 (involved most of the time).

Statistical Analysis

The groups were compared on the number of hospitalizations, emergency room visits, and outpatient procedures during the study period using Kruskal-Wallis tests, and multiple comparisons were completed when appropriate using the Dunn procedure. Nonparametric analysis of covariance (ANCOVA) was performed to compare the 3 groups on selected measures from the postprotocol

MDS data, where the preprotocol measure of the outcome variable was included in the model as a covariate. *P* values less than .05 were considered to indicate statistical significance. Statistical analyses were conducted using SAS software (version 9.2; SAS Institute, Inc, Cary, North Carolina).

Results

A total of 49 nursing home residents were screened for eligibility to participate in the study; 6 did not meet eligibility criteria, 6 requested to participate but were not enrolled because the attending physician's approval was not received until after the enrollment cutoff date, and 15 declined to participate. Of the 22 participants enrolled in the study, 21 participants completed the study—8 in the OMT group, 6 in the LT group, and 7 in the TAU group. One participant from the LT group was withdrawn from the study by the research team because of prolonged increased agitation with dementia that resulted in the participant being uncooperative with the physical examination and protocol. The mean (standard deviation [SD]) age was 87 (7) years, ranging from 74 to 96 years. Of the 21 participants who completed the study, 18 (86%) were women, 21 (100%) were white, 17 (81%) had a high school education or less, 18 (86%) were widowed, 2 (10%) were married, and 1 (5%) was divorced.

Data on hospitalizations, emergency room visits, outpatient procedures, and mortality are presented in *Table 1*. There was a significant difference between the groups on the number of hospitalizations during the study period ($P=.04$), with the OMT and LT groups having fewer hospitalizations (0 in both groups) than the TAU group (3 participants had 1 or more hospitalizations). There was no significant difference between the groups for the number of emergency room visits ($P=.38$) or outpatient procedures ($P=.62$). No participants died during the study period.

The preprotocol MDS data were collected between 1 and 77 days (mean [SD], 37 [24] days) prior to enrollment in the study. The postprotocol MDS data were collected between 188 and 265 days (mean [SD], 227 [25] days) after enrollment for the TAU group and between 41 and 121

Table 1.
Comparison of Health Outcomes and Mortality
Among Elderly Nursing Home Residents by Group

Outcome Measure, No. (%)	OMT Group (n=8)	LT Group (n=6)	TAU Group (n=7)	<i>P</i> Value
Hospitalizations ^a	0	0	3 (43)	.04
Emergency department visits ^a	1 (13)	1 (17)	3 (43)	.38
Outpatient procedures ^a	4 (50)	1 (17)	3 (43)	.62
Deaths	0	0	0	NA

^a One or more incidents.
Abbreviations: LT, light touch; NA, not applicable; OMT, osteopathic manipulative treatment; TAU, treatment as usual.

Table 2.
Comparison of MDS Physical Functioning Measures
Among Elderly Nursing Home Residents by Group

MDS Item	Form	OMT Group (n=8)	LT Group (n=6)	TAU Group (n=7)	P Value
ADL Dependence, median (Q1-Q3) ^a	Preprotocol	23 (18.5-47)	50 (45-51)	53 (15-53)	.25
	Postprotocol	21 (15-48)	49 (49-49)	51 (14-54)	.19
Passive Range of Motion, median (Q1-Q3) ^b	Preprotocol	0 (0-2)	0 (0-1)	0 (0-1)	.70
	Postprotocol	0.5 (0-1.5)	0 (0-2)	0 (0-1)	.79
Voluntary Movement, median (Q1-Q3) ^b	Preprotocol	0 (0-1)	0 (0-1)	0 (0-1)	.88
	Postprotocol	0.5 (0-1)	0 (0-1)	0 (0-1)	.82
Accidents, No. (%)					
Falls in past 30 days	Preprotocol	1 (13)	3 (50)	2 (29)	.32
	Postprotocol	0	2 (33)	1 (14)	.26
Falls in past 31-180 days	Preprotocol	3 (38)	3 (50)	4 (57)	.75
	Postprotocol	3 (38)	3 (50)	2 (29)	.60

^a The activities of daily living (ADL) dependence measure was calculated from the 11 self-performance and support assessment scores from items G1 (Activities of Daily Living Assistance) and G2 (Bathing) on the Minimum Data Set (MDS) form, version 2.0. The ADL dependence measure could range from 11 (total independence) to 55 (total dependence).

^b The passive range of motion measure and voluntary movement measure were calculated as the sum of the scores recorded for item G4 (Functional Limitation in Range of Motion) sections A (Range of Motion) and B (Voluntary Movement), respectively, on the MDS form, version 2.0. The total passive range of motion measure and the voluntary motion measure could range from 0 (no limitation/loss) to 12 (full limitation/loss).

Abbreviations: LT, light touch; OMT, osteopathic manipulative treatment; Q1, first quartile or 25th percentile; Q3, third quartile or 75th percentile; TAU, treatment as usual.

days (mean [SD], 79 [28] days) after the last intervention for the OMT and LT groups. There were no significant differences between the groups on the timing of the preprotocol ($P=.26$) and postprotocol ($P=.44$) MDS data collections.

Data from the MDS assessments are presented in *Table 2* (physical functioning measures), *Table 3* (cognition and affect measures), and *Table 4* (health care utilization measures). The groups were not significantly different on the selected MDS data before enrollment ($P>.14$) (*Table 2*, *Table 3*, and *Table 4*). There was a significant difference between the groups on the number of medications used at the end of the study ($P=.02$); fewer medications were used by the OMT group (median [first and third quartile (Q1-Q3)], 11 [9.5-11.5] medications) and LT group (median [Q1-Q3], 11.5 [7-15] medications) than the TAU group (median [Q1-Q3], 16 [12-19] medications). There were no significant differences between the groups on any of the other measures from the MDS data ($P>.06$).

Comment

The current pilot study demonstrated that the OMT and LT groups had reduced hospitalizations and medication usage compared with the TAU group during the study period. Because there was no mortality during the study, that outcome could not be compared. These results demonstrate that the study protocol is technically feasible and can be repeated using a larger number of participants.

Elderly nursing home residents are a population in

generally poor health. According to the most recent National Nursing Home Survey³³ from 2004, the most common diagnoses in this population are mental disorders, such as senile dementia; diseases of the nervous system, such as Parkinson disease; diseases of the circulatory system, such as heart disease; and diseases of the musculoskeletal system, such as osteoarthritis and osteoporosis. More than 60% of nursing home residents come from a facility that was providing them with some level of assisted living, such as an acute care hospital or assisted living facility.³³ Further, 47.9% of nursing home residents are taking 9 or more medications on a regular basis, 22.7% report pain in a 7-day period, and 1.6% are independent on all ADL measures, such as bathing, personal hygiene, ambulation, and eating.³³ Finally, 88.3% of nursing home residents are aged 65 years or older.³³ In the United States, the average life expectancy of people aged 65 and 80 years is 19 and 9 years, respectively. The life expectancy of people aged 100 years is 2.6 years.³⁴ Seasonal variation in mortality among the elderly is widely known. Deaths due to ischemic heart disease, cerebrovascular disease, and respiratory diseases peak during the late winter months, and deaths due to all causes peak in January.¹³⁻²⁸ This seasonal variation is the reason the current study was conducted during the fall and winter months. The nursing home population has much to gain if regular OMT can decrease morbidity and thereby reduce mortality.

Although OMT has been used in nursing homes for many years in the osteopathic medical profession, few

Table 3.
Comparison of MDS Cognitive and Affect Measures Among Elderly Nursing Home Residents by Group

MDS Item	Form	OMT Group (n=8)	LT Group (n=6)	TAU Group (n=7)	P Value
Memory, No. (%)					
Short-term problems	Preprotocol	7 (88)	4 (67)	5 (71)	.64
	Postprotocol	7 (88)	5 (83)	3 (43)	.07
Long-term problems	Preprotocol	4 (50)	1 (17)	2 (29)	.42
	Postprotocol	3 (38)	1 (17)	3 (43)	.32
Cognitive Skills for Daily Decision Making, Moderately or Severely Impaired, No. (%)	Preprotocol	4 (50)	3 (50)	1 (14)	.43
	Postprotocol	3 (38)	2 (33)	1 (14)	.83
Delirium, median (Q1-Q3)^a	Preprotocol	0 (0-0.5)	0 (0-1)	0 (0-1)	.69
	Postprotocol	0 (0-0)	0 (0-0)	0 (0-0)	>.99
Mood, median (Q1-Q3)^b	Preprotocol	1 (0-1)	0.5 (0-1)	0 (0-1)	.85
	Postprotocol	0 (0-0)	0 (0-0)	0 (0-0)	.38
Time Involved in Activities, median (Q1-Q3)^c	Preprotocol	2 (2-2)	2 (2-2)	2 (2-2)	.44
	Postprotocol	2 (2-2)	2 (2-2)	2 (2-2)	NA

^a The delirium measure was calculated as the sum of the scores recorded for item B5 (Indicators of Delirium) on the Minimum Data Set (MDS) form, version 2.0. The total delirium measure could range from 0 (no behaviors present) to 12 (new onset of all behaviors assessed).

^b The mood measure was calculated as the number of indicators scored as exhibited from item E1 (Indicators of Depression, Anxiety, Sad Mood) on the MDS form, version 2.0. The total mood measure could range from 0 (no behaviors exhibited) to 16 (all behaviors exhibited at least once in the last 30 days).

^c The time involved in activities measure was calculated using the scores recorded for item N2 (Average Time Involved in Activities) on the MDS form, version 2.0. The time involved in activities measure could range from 0 (not involved) to 3 (involved most of the time).

Abbreviations: LT, light touch; NA, not applicable; OMT, osteopathic manipulative treatment; Q1, first quartile or 25th percentile; Q3, third quartile or 75th percentile; TAU, treatment as usual.

outcome studies have been completed. In a 2004 pilot study investigating the use of OMT to improve the immune response to the influenza vaccine in nursing home residents, Noll et al³⁵ found that the group treated with OMT had no significant differences in antibody titers compared with a sham group, but the OMT group did have a statistically significant reduction in antibiotic usage and improved geriatric depression scores for the 16 weeks after the protocol period. Noll et al³⁶ also evaluated the side effects of an OMT protocol vs a sham protocol in a small group of nursing home residents (n=14). Six of 7 participants in each group reported that they enjoyed the treatment received. One of 7 participants in each group reported soreness from the treatment.³⁶

In the older adult population living outside the nursing home, OMT has been evaluated for its effect on pulmonary function,³⁷ on functional status after arthroplasty,³⁸ on shoulder range of motion,³⁹ and as adjunctive treatment for pneumonia.^{36,40-42} For pulmonary function, OMT was evaluated as part of the treatment for patients with chronic obstructive pulmonary disease, and results showed that certain OMT techniques resulted in increased air trapping but an overall subjective improvement in breathing.³⁷ For the use of OMT during rehabilitation after hip or knee arthroplasty, no significant effects of OMT as performed

by osteopathic medical students were found on the functional outcome measures.³⁸ When using OMT for decreased shoulder range of motion, improvement was found with OMT compared with no treatment.³⁹ Regarding adjunctive OMT for pneumonia, 2 studies have demonstrated that OMT groups had statistically significant shorter intravenous antibiotic usage and hospital length of stay when compared with standard treatment groups.^{41,42} The more recent Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE) also saw a decrease in mortality in the OMT group.⁴¹ The current study used an OMT protocol similar to these pneumonia studies^{36,40-42} and demonstrated similar findings of decreased medication usage and decreased hospitalizations. However, as the current study was a pilot study, it lacked sufficient statistical power to establish conclusive evidence.

The current study also used a LT protocol similar to these pneumonia studies.^{36,40-42} In 2 studies that used a sham (ie, LT) protocol, most participants did not know whether they received OMT or a sham protocol, or they were incorrect when guessing which treatment they had received.^{36,37} In the current study, the LT group was expected to show improved outcomes compared with the control group, and this expectation was confirmed in the results. Although there was no intent to treat, the physical contact

Table 4.
Comparison of MDS Health Care Utilization Measures Among Elderly Nursing Home Residents by Group

MDS Item	Form	OMT Group (n=8)	LT Group (n=6)	TAU Group (n=7)	P Value
Infections, No. (%) ^a	Preprotocol	0	1 (17)	1 (14)	.52
	Postprotocol	3 (38)	2 (33)	3 (43)	.95
Pain Symptom, median (Q1-Q3) ^b	Preprotocol	0, 0-0	0, 0-1	0, 0-2	.56
	Postprotocol	0, 0-0	0, 0-0	0, 0-0	.62
Stability of Conditions, No. (%)	Conditions/diseases make resident's status unstable				
	Preprotocol	1 (13)	3 (50)	2 (29)	.32
	Postprotocol	0	1 (17)	0	.61
	Acute episode or flare-up of recurrent/chronic problem				
Preprotocol	0	0	0	NA	
Postprotocol	1 (13)	0	0	.44	
Number of medications, median (Q1-Q3) ^c	Preprotocol	11.5 (10.5-13.5)	13 (7-14)	14 (10-20)	.62
	Postprotocol	11 (9.5-11.5)	11.5 (7-15)	16 (12-19)	.02
Overall Changes in Care Needs, Improvement, No. (%)	Preprotocol	1 (13)	0	1 (14)	.53
	Postprotocol	1 (13)	0	1 (14)	.44

^a One or more.
^b The pain symptom measure was calculated as the product of the scores recorded for item J2 (Pain Symptoms) on the Minimum Data Set (MDS) form, version 2.0. The total pain symptom measure could range from 0 (no pain) to 6 (daily horrible or excruciating pain).
^c Used in past 7 days.

Abbreviations: LT, light touch; NA, not applicable; OMT, osteopathic manipulative treatment; Q1, first quartile or 25th percentile; Q3, third quartile or 75th percentile; TAU, treatment as usual.

and interaction with participants during the LT protocol was expected to have an effect. Multiple studies investigating various forms of touch have been performed in the nursing home population. Most of these studies demonstrate positive behavioral and physiological effects from touch.⁴³⁻⁴⁷ This phenomenon may explain the MOPSE study finding that the LT group, like the OMT group, saw a decrease in length of stay compared with the control group.⁴¹ Therefore, the effect of touch may also account for the findings in the current study, where the LT group along with the OMT group had decreased hospitalizations and medication usage compared with the TAU group.

The primary limitation of the current pilot study was the small sample size. Study enrollment was targeted for 36 participants, but only 22 were recruited during the active protocol period. However, investigators had to turn away several participants who wished to enroll in January after the enrollment period had closed. To ensure adequate subject enrollment in future studies, recruitment of nursing home residents should begin in July rather than August. In addition, future studies could have a more defined protocol for following up with the primary care physicians to ensure paperwork is completed in a timely manner.

A second limitation was that the local population was not naïve to osteopathic manipulative medicine. Some participants in the LT group commented to the treating

physicians that the “treatment” they received was not like the OMT they had received growing up, and they considered dropping out of the study. Conversely, several participants in the OMT group asked to continue receiving OMT after the study period ended, while none of the participants in the LT group asked to continue treatment.

A third limitation was that the treating physicians found the LT protocol very challenging. These physicians perform OMT every day in their clinical practices with the intent to normalize structure and function. Physicians had to pay constant attention to the LT protocol to avoid reverting to a clinically productive form of OMT. Given the difficulty the treating physicians had while performing the LT protocol and the evidence that it may be flawed as a sham protocol, the investigators intend to revise the LT protocol to be similar to a Swedish massage LT protocol published in 2010. Rapaport et al⁴⁸ devised an LT protocol that used the back of the hand to lightly touch the same body areas in which the treatment group received Swedish massage. The Swedish massage group showed statistically significant changes in biological markers after treatment, while the LT group showed no changes compared with preprotocol values.

A fourth potential limitation of the current study was the use of the MDS assessments as a source of health-related data. The data from these assessments influence

the payment that the nursing home receives for the care of the nursing home resident. Improved resident health may decrease payments to the nursing home. However, this potential financial conflict may also be viewed as a strength of the findings in this study, because the nursing homes' MDS coordinators had no financial motive to report improved health. Additionally, the MDS assessments do not assess for localized musculoskeletal changes, which may occur in response to OMT. Thus, MDS data are acceptable only for assessing broader changes in health status. Finally, the timing of MDS assessments varied with each participant. Because MDS assessments are completed quarterly, the MDS data of some participants were collected more than 2 months prior to initiation of the protocol and up to 4 months after completion of the treatment protocol. For a future study, the investigators will attempt to standardize the timing of the MDS assessments.

A final limitation involved the participant stratification. Initial analysis of the ADL self-performance scores suggested that the OMT group statistically significantly outperformed the LT and TAU group throughout the study. Further comparison between groups revealed that the OMT group had higher ADL scores prior to enrollment than the other groups. When nonparametric ANCOVA was used to compare participants with the same ADL scores between groups, the difference was not significant. This initial difference in ADL scores may have impacted the findings, so the investigators propose substituting the ADL self-performance measure in place of sex and age in the stratification of the participants in the next study.

Andrew Taylor Still, MD, DO, never advocated for OMT to be the sole treatment for all illnesses; he believed OMT should be part of an approach designed to maximize the body's ability to heal itself.⁴⁹ In the current study, OMT was adjunctive to standard care. We attempted to isolate OMT as a specific variable in the care of elderly nursing home residents during a time of year when they appear the most prone to life-threatening illnesses. However, because the number of participants recruited was small, the next step is to repeat this study using a larger number of participants and refined LT protocols.

A reduction in morbidity and mortality in this population may impact health care costs. In 2008, the mean hospitalization cost for an individual aged 65 years or older was \$11,319.⁵⁰ The prevention of 1 hospitalization through the use of OMT in this study would have covered the costs of the physical examinations and the OMT for all OMT group participants in this study. If routine OMT demonstrates a positive impact on the morbidity and mortality of nursing home residents, then osteopathic physicians may be encouraged to hone their OMT skills to the benefit of their patients.

Conclusion

In the current pilot study, OMT and LT protocols that were administered twice per month reduced hospitalizations and decreased medication usage in elderly nursing home participants. A future study with a larger number of participants and refined protocols is needed to determine the impact of OMT on the morbidity and mortality of this population.

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Appendix.

Minimum Data Set items extracted for data analysis in a pilot study of preventative osteopathic manipulative treatment in elderly nursing home residents. The complete Minimum Data Set form, version 2.0, is available on the Centers for Medicare & Medicaid Services Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS20MDSAllForms.pdf>.

Item Number	Item Name	Item Description	Item Responses
Medical Conditions			
B2	Memory	a. Short-term memory OK b. Long-term memory OK	0. Memory OK 1. Memory problem
B4	Cognitive Skills for Daily Decision Making	0. Independent 1. Modified independence 2. Moderately impaired 3. Severely impaired	
B5	Indicators of Delirium—Periodic Disordered Thinking/Awareness	a. Easily distracted b. Periods of altered perception or awareness of surroundings c. Episodes of disorganized speech d. Periods of restlessness e. Periods of lethargy f. Mental function varies over the course of the day	0. Behavior not present 1. Behavior present, not of recent onset 2. Behavior present over last 7 days appears different from resident's usual functioning
E1	Indicators of Depression, Anxiety, Sad Mood	<i>Verbal Expressions of Distress</i> a. Resident made negative statements b. Repetitive questions c. Repetitive verbalizations d. Persistent anger with self or others e. Self-deprecation f. Expressions of what appears to be unrealistic fears g. Recurrent statements that something terrible is about to happen h. Repetitive health complaints i. Repetitive anxious complaints/concerns (non-health related) <i>Sleep-Cycle Issues</i> j. Unpleasant mood in morning k. Insomnia/change in usual sleep pattern <i>Sad, Apathetic, Anxious</i> l. Sad, pained, worried facial expressions m. Crying, tearfulness n. Repetitive physical movements <i>Loss of Interest</i> o. Withdrawal from activities of interest p. Reduced social interaction	0. Indicator not exhibited in last 30 days 1. Indicator of this type exhibited up to 5 days a week 2. Indicator of this type exhibited daily or almost daily (6, 7 days a week)
G4	Functional Limitation in Range of Motion	a. Neck b. Arm—including shoulder or elbow c. Hand—including wrist or fingers d. Leg—including hip or knee e. Foot—including ankle or toes f. Other limitation or loss	(A) <i>Range of Motion</i> 0. No limitation 1. Limitation on 1 side 2. Limitations on both sides (B) <i>Voluntary Movement</i> 0. No loss 1. Partial loss 2. Full loss

(continued)

Appendix (continued).

Item Number	Item Name	Item Description	Item Responses
Medical Conditions (continued)			
I2	Infections	<ul style="list-style-type: none"> a. Antibiotic resistant infection b. Clostridium difficile c. Conjunctivitis d. HIV infection e. Pneumonia f. Respiratory Infection g. Septicemia h. Sexually transmitted diseases i. Tuberculosis j. Urinary tract infection in last 30 days k. Viral hepatitis l. Wound infection m. None of above 	
J2	Pain Symptoms	<ul style="list-style-type: none"> a. Frequency with which resident complains or shows evidence of pain b. Intensity of pain 	<p><i>Frequency</i></p> <ul style="list-style-type: none"> 0. No pain 1. Pain less than daily 2. Pain daily <p><i>Intensity</i></p> <ul style="list-style-type: none"> 1. Mild pain 2. Moderate pain 3. Times with pain are horrible or excruciating
J4	Accidents	<ul style="list-style-type: none"> a. Fell in last 30 days b. Fell in last 31-180 days c. Hip fracture in last 180 days d. Other fracture in last 180 days e. None of above 	
J5	Stability of Conditions	<ul style="list-style-type: none"> a. Conditions/diseases make resident's cognitive, ADL, mood or behavior status unstable b. Resident experiencing an acute episode or flare-up of a recurrent or chronic problem c. End-stage disease, 6 or fewer months to live d. None of above 	
N2	Average Time Involved in Activities	When awake and not receiving treatments or ADL care	<ul style="list-style-type: none"> 0. Most—more than 2/3 of time 1. Some—from 1/3 to 2/3 of time 2. Little—less than 1/3 of time 3. None
Q2	Overall Change in Care Needs	Resident's overall self-sufficiency has changed significantly as compared to status of 90 days ago	<ul style="list-style-type: none"> 0. No change 1. Improved 2. Deteriorated
Medication Usage			
O1	Number of Medications	Record the number of different medications used in the last 7 days; enter "0" if none use	

(continued)

Appendix (continued).

Item Number	Item Name	Item Description	Item Responses
Activities of Daily Living (ADL)			
G1	ADL Self-Performance	a. Bed mobility b. Transfer c. Walk in room d. Walk in corridor e. Locomotion on unit f. Locomotion off unit g. Dressing h. Eating i. Toilet use j. Personal hygiene	<i>ADL Self-Performance</i> 0. Independent 1. Supervision 2. Limited assistance 3. Extensive assistance 4. Total dependence 8. Activity itself did not occur
G2	Bathing	How resident takes full-body bath/shower, sponge bath, and transfers in/out of tub/shower (exclude washing back and hair)	<i>Bathing Self-Performance</i> 0. Independent—no help provided 1. Supervision—oversight help only 2. Physical help limited to transfer only 3. Physical help in part of bathing activity 4. Total dependence 8. Activity itself did not occur during entire 7 days

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